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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions,
and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 81 FR 46677, dated July 18, 2016) is amended to reflect the reorganization of the Division of Tuberculosis Elimination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Office of Infectious Diseases, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete and replace the title and the mission and function statements for the Division of Tuberculosis Elimination (CVJE) and insert the following:

Division of Tuberculosis Elimination (CVJE). The Division of Tuberculosis Elimination (DTBE) promotes health and quality of life by preventing, controlling, and eventually eliminating tuberculosis (TB) from the United States (U.S.), and collaborates with international partners by representing the U.S. national TB program. In carrying out its mission, the Division conducts the following activities under each focus area:

(1) Administers and promotes a national program for the prevention, control, and elimination of TB; (2) supports a nationwide framework for surveillance of TB and evaluation of national TB prevention and control performance; (3) provides

programmatic consultation, technical assistance, and outbreak response assistance to state and local TB programs; (4) co-chairs and coordinates administrative support for the Federal TB Task Force, and supports and collaborates with the National Tuberculosis Controllers Association (NTCA) and the Tuberculosis Education and Training Network to promote effective national communications and coordinated feedback on urgent policy and program performance issues; (5) supports development of TB patient education materials and interventions, capacity development, and access to medical consultation; (6) provides national and supranational reference laboratory function for identification and drug susceptibility testing of *Mycobacterium tuberculosis*; (7) fosters patient-centered messages, including those regarding directly-observed therapy, to promote adherence with long-term treatment for improvements in well-being and interruption in community transmission of *M. tuberculosis*; (8) promotes targeted testing of epidemiologically-defined at-risk populations and treatment of persons with latent TB; (9) conducts epidemiologic, laboratory, behavioral, health systems, and clinical research; (10) supports patient and provider research to identify barriers and facilitators to TB services; (11) supports multicenter consortia for epidemiologic, laboratory, diagnostics, clinical, and vaccine development research; (12) develops and applies mathematical TB transmission models to forecast future incidence and prevalence trends; (13) provides leadership and formulates policies and guidelines; (14) provides technical supervision and training to federal assignees working in state, and local TB control programs; (15) develops training and educational materials, and provides technical assistance on communications and training needs; (16) participates in the development of policies and guidelines for TB prevention and control within populations at high risk, such as persons

infected with HIV or racial and ethnic minorities; (17) supports technical activities and operational research to reduce TB in foreign-born populations; (18) Represents the U.S. national TB program with regard to the global health initiatives for the prevention and control of TB and drug-resistant TB; (19) Represents the U.S. national TB control program with regard to the World Health Organization (WHO)-hosted Stop TB Partnership for implementation of the Global Plan to Stop TB and Millennium Development Goals; (20) monitors progress and trends towards TB elimination, including progress towards CDC's Healthy People 2020; (21) provides progress reports to, and solicits advice from, the Advisory Council for the Elimination of Tuberculosis (ACET); and (22) facilitates partnerships with affected communities, nongovernmental, professional, and global organizations.

Office of the Director (CVJE1). (1) Provides leadership and guidance in program planning and management, policy formulation, and development of training, surveillance, and research programs in TB; (2) directs and evaluates the operations of the Division; (3) establishes contact with, and promotes TB activities of, other organizations that have an important role to play in achieving TB elimination; (4) coordinates administrative and logistical support services for the Division; (5) provides consultation and assistance in writing reports for presentation at local, regional, national, and international scientific meetings and for publication in scientific journals; (6) coordinates and tracks materials for purposes of clearance and approval for publications and presentations; (7) presents findings at national and international scientific meetings; (8) presents Division overview at the ACET meetings; (9) collaborates and coordinates Division activities with other components of NCHHSTP and CDC; (10) provides technical support to ACET;

(11) provides administrative and technical support for STOP TB USA (previously the National Coalition for the Elimination of Tuberculosis) and the Federal TB Task Force; and (12) provides representation of the U.S. national TB program to WHO and other international entities.

Communications, Education, and Behavioral Studies Branch (CVJEB).

(1) Provides technical assistance to health departments and other health care providers in assessing and meeting their TB training, education, and communication needs;

(2) provides technical expertise to assess the impact of training and education activities by health departments; (3) provides technical assistance to health departments and other TB health care providers regarding behavioral studies research and intervention development; (4) provides consultation and assistance in coordinating TB training, education, behavioral studies and interventions, and communication activities carried out by other CDC programs, Regional Training and Medical Consultation Centers, and Stop TB USA members, and develops, markets, and maintains electronic mailing lists for persons with TB-related education, training, and communication responsibilities;

(5) provides DTBE coordination and oversight and technical information for CDC INFO;

(6) organizes and maintains scientific and non-scientific information resources related to TB; (7) conducts formative research and evaluation on approaches to patient, provider, and public education, and conducts research on individual and social factors affecting health-care seeking behavior and treatment outcomes related to TB; (8) based on research findings, develops behavioral interventions targeted to health care providers, persons with or at risk for TB, and other high-risk populations; (9) provides consultation to national organizations on behavioral research needs and study designs; on the technical transfer of

behavioral research findings into TB program practice and TB training and educational strategies; and provides consultation, technical assistance and coordination to other branches within the Division regarding development and implementation of behavioral interventions and training for branch specific activities such as Report of Verified Case of Tuberculosis, Aggregate Reports for Program Evaluation, and surveillance activities; (10) presents findings at national and international scientific meetings and develops, disseminates and evaluates training and educational materials and courses providing TB information to the scientific and public health communities, as well as the general population; (11) conducts training and education needs assessments; identifies resources available for health department TB control officers and senior managers, TB nurse consultants, TB training and education directors and for senior staff carrying out TB activities in other programs or facilities serving persons at high risk for TB; and develops, conducts, and coordinates training courses on TB for state and big city TB program managers and nurse consultants; (12) based on needs assessments, develops and conducts or coordinates training courses and materials for staff who train and/or supervise front-line TB program staff; (13) provides oversight in the planning, coordination, and maintenance of the Division's Internet and Intranet web sites; (14) conducts and/or coordinates communications programs designed to build public support and sustain public interest and commitment to the elimination of TB; (15) conducts communications research and identifies communications resources available for health department TB control officers and senior managers, TB nurse consultants, and for senior staff carrying out activities in other programs or facilities serving persons at high risk for TB; (16) provides coordination and oversight for Division responses and relations with the

media and public and serves as point of contact for telephonic, written, and electronic (e-mail) requests for information from the media and public; (17) develops, coordinates, and staffs the Division's exhibit booth at conferences/meetings; (18) provides oversight and coordination for TB-related voice and web-based TB information, training, and education resources; and (19) presents communications issues to ACET and at national and international scientific meetings.

Data Management, Statistics, and Evaluation Branch (CVJEC). (1) Provides Division-wide leadership in and coordination of data management, statistics, program evaluation, and economic planning, policy development, and monitoring within an integrated systems framework, playing a central role in the education of all DTBE staff on the science and methods of data management, statistics, program evaluation, and health economics; (2) consults and assists in appropriate data collection, management, analysis, and reporting for scientific studies conducted Division-wide; (3) collaborates in the statistical analysis of data and in the preparation of materials for publication; (4) coordinates and oversees data management and statistical design, implementation and analysis support, and consultation for the TB Clinical Trials and the TB Epidemiologic Studies Consortia; (5) conducts statistical research and methods development, including mathematical models of TB transmission and diagnostic test performance to improve the effectiveness of prevention and control activities; (6) coordinates data management, statistics, and evaluation services provided under contractual services; (7) collaborates with other components of the Division to develop and implement strategies and activities to meet goals for Division priorities; (8) translates overall NCHHSTP and DTBE strategies into branch-specific implementation plans for research and programs; and (9)

participates in the development of comprehensive evaluation methods for TB prevention and control programs; (10) consults on the implementation of key provisions of program evaluation contained in cooperative agreements between CDC and external state and local TB programs; (11) provides transparent and easily understood program evaluation and health economic data to TB control programs that serve them in meeting TB national goals and objectives; (12) galvanizes external TB control programs to implement and use National TB Indicators Project data to prioritize program areas for improvement; (13) provides major authoritative technical advice on economics and be an authority on all matters related to the analysis and collection of economic data relevant to Division goals, and (14) presents data management, statistical, and economic considerations, and reporting issues to ACET and other national and international scientific meetings.

Field Services Branch (CVJED). (1) Provides medical and programmatic consultation to assist state and local health departments in developing, implementing and evaluating their activities toward achieving tuberculosis prevention, control, and elimination; (2) promotes adoption of CDC tuberculosis-related policies by national organizations, health departments, and health care providers; (3) provides consultation and assists state and local health departments in the methodology and application of tuberculosis control techniques recommended by CDC; (4) provides technical assistance to states and localities for improving program operations; (5) encourages and facilitates the transfer of new technology and guidelines into clinical and public health practice; (6) serves as a liaison or focal point to assist TB programs in state and local health departments in linking with proper resource persons and obtaining technical assistance, both within and outside the Division; (7) participates in development of national policies

and guidelines for tuberculosis elimination; (8) identifies and facilitates sharing of best practices to ensure that good program methodology in one program is known and made available to other state and local programs; (9) serves as the lead branch for administration and management of cooperative agreement programs with state and local health department tuberculosis programs and others who support state and local health department tuberculosis programs; (10) develops funding opportunities based on Division strategic priorities; (11) coordinates technical reviews of cooperative agreement applications and makes appropriate funding recommendations; (12) monitors grantee performance on activities specified in the cooperative agreement; (13) identifies specific management, operational, and staff performance problems associated with not achieving TB control objectives or with not implementing essential TB components, and recommends solutions; (14) participates in the development of comprehensive evaluation methods for TB prevention and control programs; (15) collaborates with other DTBE branches in the evaluation of tuberculosis programs and development of program management and evaluation reports for publication; (16) provides supervision and support for the CDC field staff; (17) conducts a continuing analysis of the effectiveness of field personnel and utilization of other resources in relation to the tuberculosis problems; (18) provides input in to the development of Division policy, priorities and operational procedures; (19) provides programmatic oversight, technical assistance, and medical consultation to the Regional Training and Medical Consultation Centers; and (20) presents programmatic activities to ACET and at national and international scientific meetings.

Clinical Research Branch (CVJEE). (1) Assesses the need for and conducts

studies of new or existing drugs and regimens used in the prevention and treatment of TB, including dosage, duration, pharmacokinetics and toxicity; (2) supports the TB Trials Consortium in the conduct of studies of new treatments for active TB and latent TB infection; (3) supports coordinated and standardized data management for branch research, and serves as the Data and Coordinating Center for the TB Trials Consortium, collaborating as needed with both internal and external partners; (4) provides clinical support and oversight for the distribution of investigational drugs for the treatment and prevention of TB by CIOs/ Scientific Resources/Drug Service; (5) assesses the need for and conducts clinical and field trials of more specific and rapid tests to diagnose active TB and latent TB infection and to identify drug-resistant TB in collaboration with the Laboratory Branch; (6) collaborates with and provides consultation and technical assistance to national and international organizations on the design and conduct of clinical trials and research needs; (7) conducts, participates in, and collaborates with other DTBE units in research on clinical, epidemiologic, immunologic and genetic aspects of TB prevention and control; (8) collaborates with external partners in implementation of research; (9) maintains expertise and addresses special research needs relevant to drug pharmacokinetics, microbiology, drug resistant TB & special populations, including children and persons living with HIV; (10) provides consultation and training to local, state, national and international organizations and to TB program field staff, on design and conducts of clinical trials, TB therapeutics and diagnostics, health care systems research needs, decision and economic analyses, evaluation techniques, qualitative research methods, and research on TB transmission; (11) has responsibility for Divisional engagement in preparing for and participating in trials of new TB vaccines and when

appropriate, collaborates with private and public institutions in the area of vaccine development; (12) reports study results to public health practitioners through direct communication, articles in scientific journals and CDC publications, and oral and poster presentations at national and international scientific and program meetings; (13) provides input into statements and guidelines issued by the CDC, the ACET, and professional organizations; and (14) presents research issues and findings to ACET and at national and international scientific meetings.

Surveillance, Epidemiology, and Outbreak Investigations Branch (CVJEG).

- (1) Directs national surveillance of tuberculosis to provide accurate and timely national data and to monitor progress toward the elimination of tuberculosis in the U.S.;
- (2) conducts analyses of national TB surveillance data to monitor national trends in TB in order to assist in program planning, evaluation, and policy development and to identify areas for further study to guide elimination efforts; (3) conducts surveillance-related studies that evaluate current TB surveillance systems and develops new surveillance methods and systems in order to better monitor and accelerate TB elimination efforts;
- (4) provides technical surveillance expertise to state and local TB control programs, other federal agencies, and other organizations involved in TB prevention and control;
- (5) conducts epidemiologic research to assess the characteristics of persons with M. tuberculosis disease and infection in the U.S.; (6) analyzes research findings to develop improved interventions for eliminating tuberculosis and better analytic tools for future studies; (7) provides technical epidemiologic expertise to state and local tuberculosis control programs; (8) supports the TB Epidemiologic Studies Consortium in the conduct of studies of programmatically relevant epidemiologic, behavioral, economic, laboratory,

and operational research concerning the identification, diagnosis, prevention and control of TB disease and latent infection; (9) conducts molecular epidemiologic analyses of TB cases to identify, track, and guide interventions to stop TB outbreaks; (10) investigates outbreaks of tuberculosis; (11) provides consultation and technical expertise on TB surveillance, epidemiology and outbreaks to state and local tuberculosis control programs; (12) analyzes TB outbreak investigation findings in order to improve the ability of tuberculosis control programs to detect future outbreaks and respond to them promptly and appropriately to limit transmission; (13) supervises EIS officers in the conduct of their two-year assignments; (14) prepares manuscripts for publication in scientific journals; (15) presents findings at national and international scientific meetings; and (16) presents surveillance, epidemiology, and outbreak findings to ACET and at national and international scientific meetings

Laboratory Branch (CVJEJ). (1) Serves as the national reference laboratory in support of the mission of DTBE, fulfilling public health function in leadership, clinical and consultative service, and research; (2) provides laboratory support for epidemiological investigations, surveillance activities, and special studies of *Mycobacterium tuberculosis*, in collaboration with other branches; (3) administers contracts to provide *M. tuberculosis* genotyping, maintains a national database of genotypes, and conducts operational research to evaluate genotyping and optimize use of state-of-the-art methods; (4) serves as primary CDC source for reference laboratory services for *M. tuberculosis*; (5) administers grants and cooperative agreements to strengthen laboratory activities and advance testing services; (6) provides consultation, technical assistance, and training to state and municipal public health laboratories;

(7) develops, evaluates, or improves conventional and molecular methods for the detection, characterization, and susceptibility testing of *M. tuberculosis*; (8) conducts studies to define the role of bacterial virulence factors and host factors in disease processes and protection , and develops, evaluates, and improves methods for the diagnosis and prevention of TB; (9) develops experimental models of TB and conducts studies on therapy, pathogenesis, and prevention for TB; (10) prepares manuscripts for publication in scientific journals; (11) presents findings at national and international scientific meetings; (12) supervises and trains fellows in temporary or multi-year educationally-based programs in areas related to the mission of the branch; and (13) elevates awareness of laboratory issues to ACET and other stakeholders.

Sherri Berger
Chief Operating Officer
Centers for Disease Control and Prevention

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